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## COVID-19 Vaccine Information Brief

July 12, 2023

### IMPORTANT/NEW COVID-19 Vaccine Information

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### Update on COVID-19 Vaccine Commercialization

On June 15, 2023, independent experts on the Food and Drug Administration's (FDA's) Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to publicly discuss whether a change to the current vaccine strain composition of COVID-19 vaccines is necessary for the 2023-2024 fall/winter season. The VRBPAC voted to update the vaccine composition, and [FDA subsequently advised](#) those manufacturers planning to offer COVID-19 vaccines to develop vaccines with a monovalent XBB.1.5 composition. The anticipated availability of such vaccines is mid to late September 2023. These vaccines will be the first COVID-19 vaccines to be available directly from the manufacturers as part of the commercial market, rather than through the United States Government (USG).

This information is for planning purposes only based on potential, future action by FDA and CDC should new COVID-19 vaccines be authorized and recommended this fall. Details may change. **The Iowa Immunization Program will continue to update Iowa healthcare providers as soon as additional details become available.**

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## COVID-19 Vaccine Inventory and Disposal

Healthcare providers should maintain current inventories of EUA and/or BLA vaccines until the vaccine exceeds its shelf life, or the FDA announces a change to EUAs and/or BLAs, whichever occurs first. Any vial of vaccine that exceeds the shelf-life indicated by the manufacturer should be disposed of as regulated medical waste in consultation with the manufacturer. The COVID-19 Vaccination Provider Agreement states that providers should dispose of COVID-19 vaccine waste in accordance with local regulations and processes currently being used to dispose of regulated medical waste. This agreement requires providers to report wastage, including doses disposed of due to expiration.

The federal government does not have a method to return wasted or expired COVID-19 vaccines. To minimize the risk of administration error, providers should:

- Dispose of all expired COVID-19 vaccine vials in accordance with local, state, and federal regulations.
- Report all disposed inventory as “Open vial but all doses not administered”. Healthcare providers can use the IRIS [Adjusting COVID-19 Vaccine Inventory for Wastage](#) instructions to account for these doses. IRIS staff are available to help manage IRIS inventory by calling 800-374-3958.

## Resources

[Moderna Vial Expiration Checker](#)

[Pfizer Expiry Tool](#)

[Novavax Expiry Date Checker](#)

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## COVID-19 Ancillary Kits

**Once the commercialization of COVID-19 vaccine occurs, ancillary kits will NO LONGER be provided free of charge by the USG.** Providers should maintain inventory of ancillary kits to continue administration of vaccinations to anyone who is eligible and wants an authorized vaccination.

The expiration date printed on the exterior box of the ancillary kit does not apply to all the items contained in the kit. The expiry date found on the external label is based on the earliest expiry of any of the kit components. Providers may exercise discretion and continue using unexpired components (e.g., needles and syringes) until expiry of the component. Providers should dispose of expired components in accordance with local, state, and Federal requirements.

Unexpired ancillary kits or items contained within can be shared domestically, at no charge, with other immunization programs within the practice, clinics and other sites offering healthcare services, or veterinary clinics. ***The Iowa Immunization Program has no means to collect or dispose of ancillary supplies not utilized at the local level.***

Ancillary kits cannot be donated outside of the U.S. or to organizations that will use the supplies outside the U.S.

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### **VFC Program and COVID-19 Vaccine**

Children eligible for the Vaccines for Children (VFC) Program will be able to receive COVID-19 vaccines through the existing VFC program. The anticipated availability of COVID-19 vaccines through the VFC Program is mid to late September 2023 which is consistent with the anticipated COVID-19 vaccine commercialization.

VFC program eligibility includes those who are younger than 19 years of age and are Medicaid-eligible, uninsured, or underinsured with respect to vaccination (when served at Federally Qualified Health Centers or Rural Health Clinics) or are American Indian or Alaska Native. **More information regarding vaccine indications, vaccine availability and ordering instructions will be provided as soon as available.**

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### **Bridge Access Program for COVID-19 Vaccines**

**Uninsured adults** (19 and older) will be able to receive COVID-19 vaccines through a new, temporary program called the Bridge Access Program for COVID-19 Vaccines and Treatments. This program consists of two components:

- Providing COVID-19 vaccine to uninsured adults at local public health agencies and select FQHCs.
- Federal contracts with pharmacy chains that will enable the continuation of free COVID-19 vaccinations to the uninsured through network or retail locations as has been done during the COVID-19 public health emergency.

The Iowa Immunization Program anticipates receiving limited doses of COVID-19 vaccine for the uninsured adult population. Further details will be released to LPHAs and select FQHCs once program details have been finalized.

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## Anticipated COVID-19 Vaccine Schedule for Fall

Details on the current recommended vaccine schedules for each age group can be found on the [CDC website](#). An updated recommendation for all age groups is expected in the mid to late September timeframe after anticipated FDA regulatory authorizations or approvals of an updated COVID-19 vaccine composition.

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## Public Readiness and Emergency Preparedness Act (PREP Act) Declaration

The [PREP Act and the PREP Act Declaration](#) issued by the Secretary of the U.S. Department of Health and Human Services authorize and provide liability protections to licensed providers and others identified in the declaration to administer COVID-19 vaccines authorized or approved by FDA, including COVID-19 vaccines authorized for administration to children. In accordance with the recent PREP Act Amendment II, neither the end of the COVID-19 public health emergency on May 11, 2023, nor the discontinuation of USG COVID-19 vaccine distribution, affect the protections of the PREP Act declaration for COVID-19 vaccines. This authorization preempts state requirements that would otherwise prohibit, or effectively prohibit, these providers from administering the vaccine. The PREP Act Declaration authorizes certain providers listed in the Declaration to administer vaccines regardless of state requirements

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## Action Steps for Iowa COVID-19 Providers

The Iowa Immunization Program acknowledges many details regarding the commercialization of COVID-19 vaccines have not been released from the USG. The Program encourages COVID-19 providers to take the following action steps to prepare for the commercialization of COVID-19 vaccines. The Program remains committed to providing updates as information becomes available.

- **Plan to use existing inventory as much as possible.**
  - **Many individuals will wait to receive a COVID-19 vaccine until the updated version is released, as it is expected to provide more robust protection against currently circulating variants.** The Iowa Immunization Program encourages providers to continue efforts to minimize unnecessary wastage; however, they should not miss any opportunities to vaccinate every eligible person who requests a vaccination, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose in the vial.
- **Collaborate to redistribute COVID-19 vaccine inventory to prevent vaccine wastage.**
  - Instructions for LPHAs to view provider IRIS inventory, along with COVID-19 Vaccine

inventory maps, are posted to the HAN \*3 COVID-19 Vaccine folder under the \*I Vaccine Inventory Maps.

- **Continue to monitor inventory and vials of vaccine** that exceed the shelf-life indicated by the manufacturer should be disposed of as regulated medical waste in consultation with the manufacturer.
  - Report all disposed inventory as “Open vial but all doses not administered”. Healthcare providers can use the IRIS [Adjusting COVID-19 Vaccine Inventory for Wastage](#) instructions to account for these doses. IRIS staff are available to help manage IRIS inventory by calling 800-374-3958.
- **Share ancillary kits or items contained within, with other immunization programs within the practice, clinics and other sites offering healthcare services, or veterinary clinics.** Ancillary kits cannot be donated outside of the U.S. or to organizations that will use the supplies outside the U.S. The Iowa Immunization Program has no means to collect or dispose of ancillary supplies.